

\* Required fields

## Prior and Concomitant Medications

\* Name of Site: \_\_\_\_\_

\* Type of Visit: \_\_\_\_\_

e.g. Screening, Baseline, 6 months, 12 months,  
18 months, 24 months, 30 months, 36 months, 42 months, 48  
months, 54 months, 60 months.

\* Date of Visit: \_\_\_\_\_

\* GUID: \_\_\_\_\_

\* Age of Subject (years and months): \_\_\_\_\_

Subject ID: \_\_\_\_\_

Please list any medications that the subject has taken within 30 days of the study

### Parkinson's Disease Medication List

Parkinson's disease medication name: Carbidopa/levodopa/entacapone (Stalevo), Pramipexole (Mirapex), Pramipexole extended release (Mirapex ER), Ropinirole (Requip), Ropinirole extended release (Requip XL), Rotigotine transdermal patch (Neupro), Apomorphine (Apokyn), Selegiline (Eldepryl), Selegiline orally disintegrating (Zelapar), Selegiline transdermal patch (Emsam), Rasagiline (Azilect), Pergolide (Permax), Bromocriptine (Parlodel), Rivastigmine (Exelon), Trihexyphenidyl (Artane, Tremin), Benztropine (Cogentin), Biperiden (Akineton)

Medication Name (Trade or generic name)	Dose	Dose Units	Frequency	Route*	Start Date (mm/dd/yyyy)	End Date (mm/dd/yyyy)	Hours and minutes since last dose
					___/___/20___	___/___/20___	
					___/___/20___	___/___/20___	

Medication Name (Trade or generic name)	Dose	Dose Units	Frequency	Route*	Start Date (mm/dd/yyyy)	End Date (mm/dd/yyyy)	Hours and minutes since last dose
					___/___/20___	___/___/20___	
					___/___/20___	___/___/20___	
					___/___/20___	___/___/20___	

\*Select from the following for medication route: Buccal, Inhaled, Intramuscular, Intravenous, Nasal, Oral, Rectal, By ear, Topical, Subcutaneous, Sublingual, Transdermal, Other please specify

## Other Medications

Medication Name (Trade or generic name)	Indication (If given for AE, enter exact term from AE CRF)	Dose	Dose Units	Frequency	Route*	Start Date (mm/dd/yyyy)	End Date (mm/dd/yyyy)	Ongoing?
						___/___/20__	___/___/20__	<input type="checkbox"/> Yes <input type="checkbox"/> No
						___/___/20__	___/___/20__	<input type="checkbox"/> Yes <input type="checkbox"/> No
						___/___/20__	___/___/20__	<input type="checkbox"/> Yes <input type="checkbox"/> No
						___/___/20__	___/___/20__	<input type="checkbox"/> Yes <input type="checkbox"/> No
						___/___/20__	___/___/20__	<input type="checkbox"/> Yes <input type="checkbox"/> No
						___/___/20__	___/___/20__	<input type="checkbox"/> Yes <input type="checkbox"/> No

## **Prior and Concomitant Medications CRF Module Instructions**

### **GENERAL INSTRUCTIONS**

Collecting medications taken prior to the study in a defined time window (e.g., 30 days) is important when there may be potential interactions with the study intervention. Thus, a potential participant/subject may need to stop a medication prior to starting the study intervention (washout period). Furthermore, the study exclusion criteria may identify drugs that cannot be taken during the study and so prior medications are identified to determine whether an individual may be eligible for the study.

Collecting concomitant medications taken during a study is also important for safety reasons. Some drugs may interact with the study intervention and must not be taken during the study. Additionally, there may be some drugs that are not known to interact with the study intervention and may be identified through an adverse event. It may be helpful to ask study participants/subjects or their caregivers to bring prescription and over-the-counter medications to follow-up visits so that the medications can be more easily and accurately recorded on the CRF.

The Prior and Concomitant Medications form should be filled out at the baseline visit and every study visit/time point thereafter.

Studies that plan to submit their data to regulatory authorities are recommended to code their medication data using a standard terminology such as RXNorm.

### **SPECIFIC INSTRUCTIONS**

*Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.*

- **Any Medications?** – Choose one. If this question is answered YES then at least one prior/concomitant medication record needs to be recorded. Do NOT record study medications taken (if study has a drug intervention) on this form. Refer to the Study Drug Dosing form to record study medications.
- **Medication Name** – Record the verbatim name (generic or trade name) of the medication the participant/subject reports taking. See the data dictionary for additional information on coding the medication name using RXNorm.
- **Indication** – Record the reason the participant/subject gives for taking the medication. If given for an AE, enter exact term from Adverse Event CRF.
- **Dose** – Record the strength and units of the medication the participant/subject is taking.
- **Dose Units** - Record the units of the medication the participant/subject is taking. See the data dictionary for additional information on coding the dosage unit of measure using Unified Code for Units of Measure (UCUM).

- **Frequency** - Record how often the medication is being taken. See the data dictionary for additional information on coding the frequency using CDISC SDTM Frequency Terminology.
- **Route** – Record the route of administration. Acceptable responses for Route are shown below the medication table.
- **Start Date and Time** – Record the date (and time if applicable to the study) the participant/subject started taking the medication. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database. Start Date can be used to distinguish between prior medications and concomitant medications. Studies that need to collect Start Time will need to add fields for time to the form template.
- **End Date and Time** – Record the date (and time if applicable to the study) the participant/subject stopped taking the medication. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database. End Date should be recorded if Continuing Medication is answered NO. Conversely, End Date should remain blank if Continuing Medication is answered YES. Studies that need to collect End Time will need to add fields for time to the form template.
- **Ongoing?** – Choose one. Answer YES if the participant/subject is still taking the medication or NO if the participant/subject has stopped taking the medication.



